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## Conducting Clinical Trials in China Requires Compliance at Home and Abroad

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China has been home to more than 1,800 clinical trials of pharmaceuticals intended for U.S. use. With its large and growing English-speaking population, the country, along with India, is a foreign clinical trial destination poised to "eclipse all the others," according to recent coverage in *Vanity Fair*.[1] The country is at the forefront of a larger trend in moving clinical trials abroad—in 2008, 80 percent of new drug applications to the U.S. Food and Drug Administration (FDA) contained data from foreign clinical trials.

China's State Food and Drug Administration oversees the conduct of clinical trials there, but U.S. companies intending to use foreign data to submit new drug applications here are also governed by U.S. regulations on Good Clinical Practice (GCP).

The regulations provide that the FDA will accept, as support for an investigational new drug application or application for marketing approval, data from “a well-designed and well-conducted foreign clinical study,” not conducted under an investigational new drug application, if GCP standards are met.[2] GCP includes, among other things, the use of an independent ethics board for review, approval and continuing oversight; clinical investigators with recognized competence; and the ability of the FDA to validate the data via on-site inspections. Above all, the study must be designed, conducted and reported in a manner that ensures credible data, accurate results and the protection of the rights, safety and well-being of trial subjects.

Securing the informed consent of trial subjects can be particularly tricky in a foreign clinical trial, where language or cultural barriers may be involved. People desperate for medical care may sign up for a placebo-controlled study without realizing the true meaning of their assent. Though somewhat remote, liability may lie under the Alien Tort Claims Act if a foreign plaintiff can prove a corporation or its investigators violated human rights law or norms.[3]

If foreign clinical data provide the sole basis for an application for U.S. marketing approval, then the applicant must ensure the foreign data are applicable to the U.S. population and U.S. medical practice; that the studies were performed by clinical investigators of recognized competence; and that the FDA can validate the data through on-site inspection at its option.[4]

As the regulations reveal, foreign clinical trials necessarily involve heightened risk and responsibilities. Given high-profile executions of Chinese officials, pharmaceutical and medical device executives in the U.S. may wonder just how far their personal liability in China may extend. China has no extradition treaty with the U.S., however, and those Chinese officials and executives executed were convicted of intentional bribery, corruption, adulteration of products and endangering the public safety. In recent years, foreigners executed in China have been convicted drug smugglers.

Stiff U.S. federal penalties remain a reality for the unwary, though, as the Department of Justice has shown recent interest in applying the Foreign Corrupt Practices Act (FCPA) to the health care sector, particularly in the exponentially growing area of foreign clinical trials. Chinese physicians are often government employees, subjecting companies dealing with them to the FCPA prohibition on offering or payment of anything of value to a foreign official for the purpose of obtaining or keeping business.

And, if foreign clinical trial data fails to hold true in the U.S., traditional U.S. drug and device liability applies here. Some scholars cite the prevalence of drug-naïve foreign populations and their limited access to medical care as realities that can skew results and present significant legal and ethical concerns before and after a foreign-tested drug

is marketed in the U.S.

Entities seeking to conduct clinical trials in China for drugs or devices for U.S. use should consider consulting with counsel knowledgeable about the U.S. and Chinese legal and regulatory environments. Such counsel, experienced with the conduct of clinical trials in the U.S. and abroad, can assist in navigating the legal and ethical hurdles inherent to designing and establishing well-conducted clinical trials overseas.

**Notes:**

[1] *See also* Dep't of Health and Human Services Office of the Inspector General, "Challenges to FDA's Ability to Monitor and Inspect Foreign Clinical Trials," Report # OEI-01-08-00510 (June 2010), *available at* http://oig.hhs.gov/oei/reports/oei-01-08-00510.pdf.

[2] 21 C.F.R. § 312.120.

[3] Chang, Esther, *Fitting a Square Peg into a Round Hole?: Imposing Informed Consent and Post-Trial Obligations on United States Sponsored Clinical Trials in Developing Countries*, Note, 11 S. Cal. Interdis. L.J. 339, 343 (Spring 2002).

[4] 21 C.F.R. § 314.106.

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